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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,798	04/10/2001	Takao Daicho	109146	8412
25944	7590	11/28/2003	EXAMINER	
OLIFF & BERRIDGE, PLC P.O. BOX 19928 ALEXANDRIA, VA 22320			PATTEN, PATRICIA A	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/828,798	DAICHO, TAKAO	
	<b>Examiner</b>	<b>Art Unit</b>	
	Patricia A Patten	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-14 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6, 8 and 11-14 is/are rejected.
- 7) ☒ Claim(s) 9 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***RCE Practice***

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114. Applicant's submission filed on 11/06/2003 has been entered.

Claims 1, 3, 4 and 6-14 are pending in the application.

Claim 7 was withdrawn from further consideration on the merits as being drawn to a non-elected invention in the Office Action of 2/26/2002.

Claims 1, 3, 4, 6 and 8-14 were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

Claim 9 is objected to because of the following informalities: Claim 9 recites 'daily does' while it is thought that Applicant intends for this to read 'daily dose'.

Claims 6 and 12 recite 'Gycyrrhiza uralensis Fisch. ))'. Here, it is thought that Applicant intends for only one parenthesis to appear after 'Fisch.'.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-14 recite additional constituents added to claims 9 or 10. These claims are indefinite in that claim 9 stated 'consisting of' which is closed language:

The transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim. In re Gray, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("consisting

of" defined as "closing the claim to the inclusion of materials other than those recited except for impurities ordinarily associated therewith."). ***A claim which depends from a claim which "consists of" the recited elements or steps cannot add an element or step*** (emphasis added) See MPEP § 2111.03.

Applicant is asked to cancel the claims, or rewrite the claims in independent form in order to overcome this rejection.

### ***Claim Rejections - 35 USC § 103***

Claims 1, 3-4 6 and 8 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Mach (US 4,487,766).

Applicant's arguments were fully considered, but not found persuasive.

Applicant argues 'As demonstrated by the TABLE, located at page 10 of the specification, this combination of cholic acid and at least one member chosen from the group consisting of isoflavones or isoflavone glycosides produces biologically synergistic effects" (pp. 6 and 8-Arguments). However, as previously indicated, the Table on page 10 of the Instant specification does not demonstrate that any particular amount of cholic acid and isoflavones act in a synergistic manner, but have shown that the combination alone produces these effects. Because the combination of cholic acid and isoflavones has this effect, the

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combination of cholic acid and isoflavone as disclosed by Mach must have had the same effect, and was thus intrinsic to the composition.

Applicant argues that Mach et al. did not specifically disclose the particular amounts of cholic acid and isoflavones. Applicant is reminded that the outstanding rejection is a 103 rejection and not a 102 rejection. Therefore, it is clear that Mach did not teach the amounts of cholic acid and isoflavones present in the claims. However, it was made clear in previous Office actions that variations of constituent amounts in animal feed was routine in the art at the time the invention was made; and thus, the amounts found in the claims would have been within the purview of the ordinary artisan, especially lacking any evidence of unexpected results with regard to these particular amounts.

Applicant again argues that Mach did not teach that the animal feed was for human use (p.6- Arguments). It is reiterated that the Instant claims are not drawn to human use: In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., human use) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Mach 'anticipates the composition that further comprises a "crude drug". This argument is moot considering the claims do not recite 'crude drug'.

Applicant argues that Ogawa does not satisfy the deficiencies of Mach because Mach did not teach the particular amounts of cholic acid and isoflavones (p.8-Arguments). As discussed *supra*, as well as in previous Office Actions, although Mach did not specifically teach the claimed amounts of cholic acid and isoflavones, the ordinary artisan would have had a reasonable expectation that these amounts would have been suitable to use as animal feed.

***Allowable Subject Matter***

Claim 10 is objected to as being dependent upon an objected base claim (claim 9) but would be allowable if claim 9 is rewritten to overcome the objection set forth *supra*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A Patten whose telephone number is (703) 308-1189. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (703) 306-3220.

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The fax phone number for the organization where this application or proceeding is assigned is (703) 872-3906.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

11/24/03

Patricia A Patten  
Examiner  
Art Unit 1654

A handwritten signature in cursive script, appearing to read "Patricia A. Patten".

**PATRICIA PATTEN  
PATENT EXAMINER**